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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,843	03/05/2002	Naoki Usui	220215US0CONT	1934

22850 7590 06/30/2003

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10 087843

Applicant(s)

USUI et al

Examiner

NGL Long

Group Art Unit

1616

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/14/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 5-17 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 5-17 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☒ received in Application No. (Series Code/Serial Number) 09/446132
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 346
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Receipt is acknowledge of pre amendment, IDS, IDS, Pre amendment and IDS (4/14/03).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7, 9-10, 12, 13, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PH adjustment with Lysine monohydrochloride, or nithine monohydrochloride or arginine monohydrochloride, does not reasonably provide enablement for General anion regulation or determination of need. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification addresses problems, milk fever, but provides no demonstration of solutions, other than of palatability, further definition of "neutral hydrochloride – compound" can lead to ambiguity, thus, those materials as supported in the specification falling in the acceptable definition should be in the claims. There is no basis for understanding "effective amount" or "ruminant in need thereof". Data presented are for calves; milk fever is not demonstrated to be reduced; only urine pH is, and this would not be desired outside of a narrow period in the lactation cycle.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rode et al EP 0610957.

Rode feeds pre partum 3 weeks, continuing 30-150 days into lactation (summary), a lysine neutral hydrochloride (p.5 line 19-24). No cows were reported as having milk fever. Amounts of the feed were in amounts effective to provide for consumption, high milk production, and health maintenance and metabolic balance (p. 5, bottom, p.6). However, urine pH was not reported.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rode et al. EP 0610957 or Sato et al 5,906842 in view of Itagaki et al 033698 and further in view of Davidson et al '95

Rode (above) feeds the instant neutral amino acid forms, Pre-partum, to Dairy cows and increases milk production, with out incidence of milk fever. However, all of the forms are not reported, nor was urine pH measured. Sato likewise feeds the instant amino acids, but not specifically identified as neutral (summary). The amounts fed are palatable, and effective (col. 3, lines 40-62, col. 4, lines 12-18). Milk production increase is seen; milk fever is not (col. 5, line 30-47). Therefore the anion/cation

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balance, urine pH must have been as in the instant invention, in the cows that need regulation. Itago is cited as describing the form of lysine, arginine and or nithine salts (p. 3, col. 4, lines 41-46, and examples 2), one can use to make the products for ruminant. Davidson show adjusting cation/anion balance avoids milks fever, and urinary pH can be measured, and maintained at 6.5-5.5 (p.634).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize amino acid feed composition, to use one of Rode or Satin order to enhance milk production in high producing cows, with out metabolic imbalance, modified by monitoring of pH in order to maintain the + anionic/cationic balance shown by Davidson as providing Ca status so as to avoid milk fever. Itagaki discloses the form of the amino acids, any of which as shown by Rode, can be fed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



NEIL S. LEVY
PRIMARY EXAMINER